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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/487,790	01/20/2000	Raphael Gorodetsky	995/46	3576

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WINSTON & STRAWN
PATENT DEPARTMENT
1400 L STREET, N.W.
WASHINGTON, DC 20005-3502

EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/487,790	GORODETSKY ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *3-9 and 13-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-21 are pending.

Election/restriction

Applicants' election (filed 8/4/04) of Group I, claims 1-6 and 10-12 and additional election of SEQ ID NO:1 peptide) with traversal for patent examination is acknowledged. The traverse is on the grounds that all claims should be considered as being directed to a single invention and that all three peptide of SEQ ID N)s: 1, 2 and 3 are homologous to each other in term of their haptotatic activity (see page 2 of the response). Applicants contest that the utility of the composition depends on one feature, i.e., haptotatic activity of each of the peptides, and thus infer that the peptides of SEQ ID Nos: 1-3 should be examined together.

Applicants' arguments have been fully considered but they are unpersuasive because of the following reasons. (1) As stated in the restriction requirement mailed 6/24/04, the compositions of Groups I-V are patentably distinct; and thus, they are not directed to a single invention. (2) The peptide sequences of SEQ ID NOs: 1, 2 and 3 are structurally distinct from one another and their structural characteristics (length, composition and sequence) do not depend upon the activity of each peptide. Note that for examination purpose, the sequence (structure) of product claims but not the activity thereof will be searched. (3) The peptide sequences of SEQ ID NOs: 1, 2 and 3 are homologous to the carboxyl terminus of the β-chain, i.e., Cβ of fibrinogen, internal γ-chain of fibrinogen, i.e., preCγ, and, C-terminus sequence of fibrinogen αE, i.e., CαE, respectively (see pages 10, 14 and 17 of the specification). Although Table 1 shows alignment of peptides of SEQ ID NOs:1-3, the specification does not set forth a common

core sequence among said peptides which is required for haptotatic activity thereof. In light of the fact that these peptides are derived from distinct/different regions (i.e., Cβ, preCγ and CαE of the fibrinogen for SEQ ID NOs:1, 2 and 3, respectively), SEQ ID NOs:1, 2 and 3 are considered to be structurally distinct from one another. Hence, the requirement is still deemed proper and is therefore made FINAL.

Claims 3-5 are directed to non-elected SEQ ID NO:2 or 3, and thus, drawn to non-elected invention. Therefore, the elected claims 1-2 and 10-12 are examined in this Office action. Claims 3-6, 7-9 and 13-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

IDS

The references cited in the information disclosure statements (IDS) submitted 4 August 2004 have been placed in the file. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

On page 17, line 14, "the carboxy terminal of the β chain" should be changed to "the carboxyl terminus of the β chain".

On page 18, lines 14-15, after each peptide sequences "KGSWYSMRKMSMKIRPFFPQQ", "KTRWYSMKKTTMKIIPFNRL" and "RGADYSLRAVMKIRPLVTQ" add "(SEQ ID NO:1)", "(SEQ ID NO:2)" and "(SEQ ID NO:3)", respectively.

On page 22, line 6, "..." should be deleted before "AAGGGG", the similar changes should be made for the nucleotide sequences of Cβ-DNA, CαE-DNA and PreCγ-DNA at lines 7, 9-10, and 12-13.

On page 14, line 11, "SB" should be spelled out in full for the first instance of use.

On page 9, the last paragraph is ambiguously set forth.

In claims 1 and 2, after "A polypeptide" comma "," should be deleted.

In claim 10, after "A composition" comma "," should be deleted. Also, in claim 10 "haptotactic peptide' should be changed to haptotactic polypeptide" because the SEQ ID NO:1 is a polypeptide as set forth in claim1.

Appropriate correction is required.

Claim Rejection under 35 USC 101

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. The claims, as written, do not sufficiently distinguish over nucleic acids, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed polynucleotide and the naturally occurring polynucleotide. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "synthesized" as indicated on page 33, Example 1 of the specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a polypeptide comprising a peptide sequence of SEQ ID NO:1 and a composition comprising said polypeptide and functional analogues which may be resulted form substitution of at least one amino acid by a non-naturally occurring amino acid. The specification does not teach a fusion protein comprising the SEQ ID NO:1 and a polypeptide that comprises substitution(s) with naturally/non-naturally occurring amino acid(s), and does not describe how to make the analogues because the specification does not teach the core sequence for SEQ ID NO:1 which is required for making the analogue. And/or, the specification does not teach a polymer comprising SEQ ID NO:1 and a chemical compound which is conjugated to a peptide in which amino acid residue(s) is substituted by naturally/non-naturally occurring amino acid(s) and does not describe how to make the polymer thereof.

Without a statement regarding structural characteristics of the functional analogues within the claimed polypeptide, one skilled in the art cannot know the metes and bounds of the claimed composition; and thus, one skilled in the art is unable to practice the claimed invention, i.e., make and use the claimed polypeptide and composition comprising said polypeptide in order

for having a haptotactic activity. Therefore, there is no structural parameter for the polypeptide and therefore the claim lacks written description.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 2 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "functional analogues thereof having at least one amino acid substitution into ..."; the recitation is unclear as to whether or not said amino acid substitution is based on SEQ ID NO:1 or otherwise peptide sequence. Also, the phrase "substitution into" appears to be awkward; does it refer to substitution by a naturally occurring or non-naturally occurring amino acid? Also, claim 2 is unclear in the phrase "functional analogues" as to whether or not said analogues are derived from entire sequence or part of SEQ ID NO:1, or from any polymer. Note that the specification does not provide sufficient definition for this phrase. Further, claim 2 is not apparent in ".... SEQ ID NO:1 and functional analogues..."; does the claimed polypeptide comprise a fusion polypeptide having SEQ ID NO;1 and analogue, or claim 2 is directed to a polypeptide comprising SEQ ID NO:1 or a polypeptide comprising the analogues thereof?

The limitation "non-naturally occurring amino acid" is not defined in this application. Note that the specification only defines "*non-regular natural* amino acid" (see page 13, lines 16-20). Does the "non-naturally occurring amino acid" encompass (i) amino acids which are

produced by a cell/organism but which is not a component of biosynthesized protein/polypeptide; the example for this is amino acid ornithine, which is not a component of protein, or (ii) any chemically synthesized amino acid?

Claim 10 sets forth SEQ ID NOs: 2 and 3 which are non-elected subject matters, which renders the claim indefinite. The dependent claims are also rejected. Thus, applicants are required to re-write the claim in order to eliminate the subject which has been withdrawn from consideration in this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 10-11 are rejected under 35 U.S.C. 102 (b) as being anticipated by Watt, K. W. K. et al. (*Biochemistry* (1979) 18, 68-76).

Watt et al. teach a polypeptide comprising the sequence of the instant SEQ ID NO:1 (see residues 471-491 of amino acid sequence shown in Figure 7, page 75), which anticipates the instant claim 1.

Claim 2 is also rejected, because claim 2 does not make it clear as to whether or not the subject matte of the claim is only directed to the polypeptide comprising SEQ ID NO:1 (see the rejection under 35 USC, second paragraph).

In Figure 1, Watt et al. teach a composition comprising said polypeptide, which anticipates the instant claim 10.

Claim 11 is included in the rejection because the Watt's polypeptide must be dissolved in an aqueous solution including water, absent factual indicia to the contrary.

Claims 1-2, 10 and 12 are rejected under 35 U.S.C. 102 (b) as being anticipated by Garner, I. et al. (WO 95/23868).

On "Summary of the invention" (page 3), Garner et al. teach recombinant fibrinogen protein encompassing α-chain, β-chain and γ-chain wherein the β-chain of SEQ ID NO:4 polypeptide is encoded by SEQ ID NO:3 polypeptide (see page 8, lines 11-12). The residues 471-491 of the Garner's SEQ ID NO:4 reads on the instant SEQ ID NO:1, which anticipates the instant claim 1.

Claim 2 is also rejected, because claim 2 does not make it clear as to whether or not the subject matte of the claim is directed to the polypeptide comprising SEQ ID NO:1 only (see the rejection under 35 USC, second paragraph).

In Example II, Garner et al. teach a composition (a transgenic animal) comprising Bβ-chain, i.e., the above-mentioned SEQ ID NO:4, which anticipates the instant claim 10.

Since the Garner' composition also comprises biological agent, e.g., growth factors (see the definition for the "biological agent on page 11), the above Garner' teaching is applied to the instant claim 12. Note that the growth factor is an inherent property of the said transgenic animal (composition).

Claims 1-2 and 10-12 are rejected under 35 U.S.C. 102 (b) as being anticipated by Koopman, J. et al. (*Proc. Natl. Acad. Sci. USA.* (1992) 89, 3478-3482).

Koopman et al. teach fibrinogen protein that comprises Bβ chain (see page 3478, the left column) wherein the Bβ chain comprises a sequence consisting of amino acid residues 471-491 (see attachment 1) which reads on the instant SEQ ID NO:1. The Koopman's teaching anticipates the instant claim 1.

The above fibrinogen protein is a dimer of three polypeptides, Aα, Bβ and γ. Thus, the above Koopman's teaching anticipates the instant claim 10.

In "Materical and Methods" section (page 3479), Koopman te al. teach that the isolated fibrinogen protein is dissolved in 0.15 NaCl solution, which anticipates the instant claim 11, as 0.15 NaCl solution is considered to be a pharmaceutically acceptable carrier.

Also, in "Materical and Methods" section (page 3479), Koopman et al. teach the above-mentioned composition further comprises a biological agent, e.g., immunoglobulin (anti-fibrinogen IgG) (See page 3479, the left column, the last paragraph), which anticipates the instant claim 12.

Further, Koopman et al. teach a purified fibrinogen protein comprising a substitution at β-chain, i.e., Arg44 →Cys (see page 3480, the left column, and page 3481, the right column, the last paragraph) which is a functional analogue to the intact fibrinogen β-chain. Because the said fibrinogen form a dimer (see statement supra), the Koopman's fibrinogen protein comprises the sequence that reads on the instant SEQ ID NO:1 and said functional analogue of the protein. The Koopman's teaching thus anticipates the instant claim 2.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel Wei Liu, Ph.D.

Art Unit 1653, Examiner

March 1, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER